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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | FIRST NAMED INVENTOR | | | |
|-----------------|-------------|----------------------|----------------------|----------|--|--|
| 09/523.532 | 03/10/0 | BARRY | D | 9045-2CT | | |

T 020792 LM71/0911 MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH NC 27627 EXAMINER
HAYES, J

ART UNIT PAPER NUMBER
2761

DATE MAILED:

09/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

020792 LM71/0911 MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH NC 27627

| APPLI | CATION NO. | FILING DATE | TOTAL CLAIMS | EXAMINER AND GR | ROUP ART UNIT | A B CONTROL OF A | DATE MAJLED / OUT |
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| <u> </u> | 09/523,53 | 2 '03/10/ | 00 066 | HAYES, J | · | 2/01 | |
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| First Named Applicant | BARRY, | | Driv | TT. M. | more milita | THE THE | CELECTI |
| TITLE OF INVENTION | SYSTEMS, M ON OF THER | ETHODS AND APEUTIC TR | COMPUTER PREATMENT REGI | RUGRAM PRODUCTS IMENS | TUK GUIP | 1 1464 - 1 1162. | |

| ATTY'S DOCKET NO. | CLASS-SUBCLASS | BATCH NO. | APPLN. T | YPE | SMALL ENTITY | | DATE DUE |
|-------------------|----------------|-----------|----------|------|--------------|-------|----------|
| 3 9045-2C | T 705 | -003.000 | 1801 | UIIL | ITY YES | かいがった | |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN <u>THREE MONTHS</u> FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

- I. Review the SMALL ENTITY status shown above. If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
 - A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
 - B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.
- II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.
- III. All communications regarding this application must give application number and batch number.

 Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees.' It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PATENT AND TRADEMARK OFFICE COPY

| | Application No. | Applicant(s) | | | | |
|--|--|---|-------------------|--|--|--|
| | 09/523,532 | PARRY ET AL | DARRY ET AL | | | |
| Notice of Allowability | Examiner | BARRY ET AL. Art Unit | - | | | |
| | John W Hayes | 2761 | | | | |
| The MAILING DATE of this communication appe | ars on the cover sheet w | vith the correspondence address | | | | |
| All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance and Issue F | (OR REMAINS) CLOSED | in this application. If not included | | | | |
| 1. This communication is responsive to Amendment filed 07 Amendment fi | <u>August 2000</u> . | | | | | |
| 2. The allowed claim(s) is/are <u>1-4,6-27,29-50 and 52-69</u> . | | | | | | |
| 3. The drawings filed on 10 March 2000 are acceptable. | | | | | | |
| 4. Acknowledgment is made of a claim for foreign priority und | | | | | | |
| a) All b) Some* c) None of the CERTIF | IED copies of the priority of | locuments have been | | | | |
| 1. Treceived. | | | | | | |
| received in Application No. (Series Code / Ser | ial Number) | | | | | |
| received in this national stage application from | the International Bureau | (PCT Rule 17.2(a)). | | | | |
| * Certified copies not received: | | | | | | |
| 5. 🔀 Acknowledgement is made of a claim for domestic priority u | ınder 35 U.S.C. & 119(e). | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY to comply w THREE MONTHS FROM THE "DATE MAILED" of this Office Action ABANDONMENT of this application. Extensions of time may be a | on. Failure to timely comp | lv will result in | | | | |
| 6. Note the attached EXAMINER'S AMENDMENT or NOTICE the oath or declaration is deficient. A SUBSTITUTE OATH | OF INFORMAL APPLICATION IS I | ATION (PTO-152) which gives reason REQUIRED. | n(s) why | | | |
| 7. Applicant MUST submit NEW FORMAL DRAWINGS | | | | | | |
| (a) Decause the originally filed drawings were declared by | applicant to be informal. | | | | | |
| (b) including changes required by the Notice of Draftspers | on's Patent Drawing Revi | ew(PTO-948) attached | | | | |
| 1) hereto or 2) to Paper No | | | | | | |
| (c) including changes required by the proposed drawing c | orrection filed , wh | ich has been approved by the examin | ner. | | | |
| (d) including changes required by the attached Examiner's | | , | | | | |
| Identifying indicia such as the application number (see 37 drawings. The drawings should be filed as a separate paper Draftsperson. | CFR 1.84(c)) should be per with a transmittal let | written on the reverse side of the ter addressed to the Official | | | | |
| 8. Note the attached Examiner's comment regarding REQUIR | EMENT FOR THE DEPO | SIT OF BIOLOGICAL MATERIAL. | | | | |
| Any reply to this letter should include, in the upper right hand corne applicant has received a Notice of Allowance and Issue Fee Due, the ALLOWANCE should also be included. | er, the APPLICATION NU the ISSUE BATCH NUMB | MBER (SERIES CODE / SERIAL NU ER and DATE of the NOTICE OF | MBER). If | | | |
| Attachment(s) | | | | | | |
| I⊠ Notice of References Cited (PTO-892) | 2 Notice | of Informal Patent Application (PTO-1 | 152) | | | |
| B Notice of Draftperson's Patent Drawing Review (PTO-948) | | w Summary (PTO-413), Paper No | · | | | |
| 5⊠ Information Disclosure Statements (PTO-1449), Paper No. <u>6</u> . 7□ Examiner's Comment Regarding Requirement for Deposit | | er's Amendment/Comment er's Statement of Reasons for Allowa | 2000 | | | |
| of Biological Material | 9☐ Other | | 1110 0 | | | |
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DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 07 August 2000 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,081,786 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Allowable Subject Matter

- 2. Claims 1-4, 6-27, 29-50 and 52-69 are allowed over the prior art of record.
- 3. The following is a statement of reasons for allowance:

As per independent claim 1, the closest prior art of record (U.S. Patent No. 5,517,405 to McAndrew; "Application of an Expert System in the Management of HIV-Infected Patients" by Pazzani et al, or "A Computer-Assisted Management Program for Antibiotics and Other Antiinfective Agents" by Evans et al) taken either individually or in combination with other prior art of record fails to teach or suggest a method for guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition, the method comprising providing patient information to a computing device specifically comprising the three distinct knowledge bases as recited and generating in a computing device a listing of available therapeutic treatment regimens based on the patient information and the first knowledge base; and generating advisory information for one or more therapeutic treatment regimens in the listing based on the patient information and expert rules. The specific allowable features not disclosed in the prior art are the use of the three distinct knowledge bases recited in this claim in combination with the listing of available treatment regimens and advisory information. Claims 2-4 and 6-23 are dependent upon claim 1 and thus have all the limitations of claim 1 and are allowable for that reason.

As per independent claim 24, the closest prior art of record (U.S. Patent No. 5,517,405 to McAndrew; "Application of an Expert System in the Management of HIV-Infected Patients" by Pazzani et al, or "A Computer-Assisted Management Program for Antibiotics and Other Antiinfective Agents" by

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Evans et al) taken either individually or in combination with other prior art of record fails to teach or suggest a system for guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition, the system comprising providing patient information to a computing device specifically comprising the three distinct knowledge bases as recited and generating in a computing device a listing of available therapeutic treatment regimens based on the patient information and the first knowledge base; and generating advisory information for one or more therapeutic treatment regimens in the listing based on the patient information and expert rules. The specific allowable features not disclosed in the prior art are the use of the three distinct knowledge bases recited in this claim in combination with the listing of available treatment regimens and advisory information. Claims 25-27 and 29-46 are dependent upon claim 24 and thus have all the limitations of claim 24 and are allowable for that reason.

As per independent claim 47, the closest prior art of record (U.S. Patent No. 5,517,405 to McAndrew; "Application of an Expert System in the Management of HIV-Infected Patients" by Pazzani et al, or "A Computer-Assisted Management Program for Antibiotics and Other Antiinfective Agents" by Evans et al) taken either individually or in combination with other prior art of record fails to teach or suggest a computer program product for guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition, the computer program product comprising a computer usable storage medium having computer readable program code means embodied in the medium for providing patient information and for generating the three distinct knowledge bases as recited and generating a listing of available therapeutic treatment regimens based on the patient information and the first knowledge base; and generating advisory information for one or more therapeutic treatment regimens in the listing based on the patient information and expert rules. The specific allowable features not disclosed in the prior art are the use of the three distinct knowledge bases recited in this claim in combination with the listing of available treatment regimens and advisory information. Claims 48-50 and 52-69 are dependent upon claim 47 and thus have all the limitations of claim 47 and are allowable for that reason.

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Conclusion

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4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

• Herren et al disclose an integrated disease management system and computer assisted methodology

for supporting the development of new medical interventions for diseases, however, fails to specifically

disclose the unique knowledge bases of the present invention as disclosed in the independent claims.

5. Any inquiry concerning this communication or earlier communications from the examiner should

be directed to John Hayes whose telephone number is (703)306-5447. The examiner can normally be

reached Monday through Friday from 5:30 to 3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd

Voeltz, can be reached on (703) 305-9714.

The Fax phone number for the UNOFFICIAL FAX for the organization where this application or

proceeding is assigned is (703) 305-0040 (for informal or draft communications, please label

"PROPOSED" or "DRAFT").

The Fax phone number for the OFFICIAL FAX for the organization where this application or

proceeding is assigned is (703) 308-9051 or 9052 (for formal communications intended for entry).

Any inquiry of a general nature or relating to the status of this application or proceeding should be

directed to the receptionist whose telephone number is (703) 305-3900.

jwh

31 August 2000

EMANUEL TODD VOEI SUPERVISORY PATENT EX

GROUP 2700